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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH
CENTRAL DIVISION

LINDA P. SMITH,

Plaintiff

v.

XAVIER BECERRA, in his capacity as the Secretary of the United States Department of Health and Human Services,

Defendant

Case No. 1:21-cv-00047-HCN-DBP

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT AND TO VACATE

JURY TRIAL DEMANDED

Judge Howard Nielson, Jr.
Magistrate Judge Dustin B. Pead

I. Introduction and Relief Sought

Pursuant to FED.R.CIV.P. 56, DUCivR 56-1, and 5 U.S.C. § 706(2)(A)/(D) (*see* Dkt. #2, Counts I and III), Mrs. Smith files this motion for summary judgment that CMS 1682-R issued illegally, seeking a declaration of the same, and vacating CMS 1682-R.[1]

II. Background

A. The Notice and Comment Provisions of the Medicare Act

Pursuant to 42 U.S.C. § 1395hh(a)(2):

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

As further provided in § 1395hh(b)(1):

> Except as provided in paragraph (2),[2] before issuing any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

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[1] The arguments in this motion are primarily directed to CMS 1682-R. However, these same arguments are equally applicable to Local Coverage Determination (LCD) L33822 and Local Coverage Article (LCA A52464) which issued the same day as CMS 1682-R and are based on it. Thus, the invalidation/vacatur of CMS 1682-R would have the effect of invalidating/precluding the enforcement of those portions of LCD L33822 and LCA A52464 that rely on it.

[2] Containing exclusions not relevant here.

In *Azar v. Alina Health Services*, 139 S.Ct. 1804 (2019), the Supreme Court confirmed that the Medicare specific notice and comment provisions of 42 U.S.C. § 1395hh applied to Medicare rather than the notice and comment provisions of the Administrative Procedure Act.

B. CMS' Rulings and CMS 1682-R

In the period prior to January 12, 2017, numerous ALJs had found CGMs met the regulatory requirements of 42 C.F.R. § 414.202 and were covered were "durable medical equipment." [3] *See, e.g.*, AR145-151, AR627-842, AR867-951, AR1415-1632, AR1657-1717, AR1909-1916, AR2139-2618, AR3742-4064, AR4089-4226, AR4857-5348, AR5601-5923, AR 5951-6091, AR6904-7103, AR7712-8033, AR8058-8195. Indeed, one ALJ had already determined that Mrs. Smith's CGM was covered "durable medical equipment." *See* AR613-625, AR1403-1412.

CMS Ruling 1682-R issued on January 12, 2017, and became effective that same day. *See* Exhibit B at 16 ("EFFECTIVE DATE: This Ruling is effective January 12, 2017. Dated: January 12, 2017. /s Patrick Conway"). Prior to January 12, 2017 (or at any time thereafter), CMS Ruling 1682-R was not published in the FEDERAL REGISTER. *See* Exhibit A at ¶8. Pursuant to 42 C.F.R. § 405.1063(b), CMS

[3] A listing of over 60 such decisions can be found at https://dparrishlaw.com/parrish-law-offices-wins-significant-victory-for-cgm-users/

Rulings "are binding on all CMS components, [and] on all HHS components that adjudicate matters under the jurisdiction of CMS." *See also* 42 C.F.R. § 401.108(c). CMS 1682-R describes CMS rulings as "precedent final opinions and orders and statements of policy and interpretation." *See* Exhibit B at 1. CMS 1682-R "articulates CMS policy concerning the classification of continuous glucose monitoring system as durable medical equipment." *Id*.

As set forth there, CMS 1682-R establishes two categories of CGMs – "therapeutic" and "non-therapeutic." "Therapeutic" CGMs are alleged to meet the regulatory requirement of "primarily and customarily used to serve a medical purpose" and are covered. *Id.* at 6-8. In order to qualify as a "therapeutic" CGM, CMS 1682-R required CGMs to "replace" home blood glucose monitors. *Id.* at 19, *e.g.* CMS 1682-R further established the category of "non-therapeutic" CGMs which are alleged to be "adjunctive" / "precautionary" (non-statutory/non-regulatory terms) and not meet the regulatory requirement of "primarily and customarily used to serve a medical purpose" and are not covered. *Id*. at 6-9.

Also on January 12, 2017, without notice and comment, Local Coverage Article (LCA) A52464 was amended to incorporate the new requirements of CMS 1682-R. *See* Exhibit C, Exhibit F at ¶37, Exhibit G at ¶37. LCAs provide codes used for billing purposes. As set forth there:

> Effective for claims with dates of service on or after January 12, 2017, Medicare covers therapeutic CGM devices under the DME

> benefit. CGM devices covered by Medicare are defined in CMS Ruling 1682R as therapeutic CGM. CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit).
>
> * * *
>
> Codes A9276 (SENSOR; INVASIVE (E.G., SUBCUTANEOUS), DISPOSABLE, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, ONE UNIT = 1 DAY SUPPLY) and A9277 (TRANSMITTER; EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM) describe the supplies used with a non-therapeutic CGM. Codes A9276 and A9277 are not used to bill for supplies used with code K0554.
>
> Code A9278 (RECEIVER (MONITOR); EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM) describes any CGM system that fails to meet the DME Benefit requirements as described in CMS Ruling 1682R.

Thus, pursuant to the LCA, anything coded A9276, A9277, or A9278 is alleged to not meet the definition of "therapeutic" set forth in CMS 1682-R and is not covered.

C. Mrs. Smith's Claims in this Case and Pending Rejection

As set forth in AR23-32 and AR38-47, ALJ Win denied Mrs. Smith's claims for coverage of her CGM and supplies on the grounds that CMS 1682-R and its definition of "therapeutic" CGMs precluded coverage. As described by ALJ Win, CMS 1682-R "controls" and "CMS Ruling 1682-R [], by law, is binding on the ALJ with regard to the claims at issue." *See, e.g.*, AR31-32.

As set forth at AR3-11, Mrs. Smith appealed ALJ Win's decisions and her claims were finally rejected by the Medicare Appeals Council (MAC). The MAC did so by agreeing "with the ALJ's rationale for non-coverage" and adopting ALJ

Win's decisions. *See* AR3. The MAC further explained its conclusion by relying on CMS 1682-R throughout its decision. *See* AR4, AR6, AR9 (through LCA A52464), and AR10.

In addition to the claims whose denial is subject to review in this case, Mrs. Smith has another pending claim that has been denied based on CMS 1682-R. In particular, on July 14, 2021, Mrs. Smith received a supply of sensors for use with her CGM. Pursuant to CMS 1682-R and LCA A52464, Mrs. Smith's claim for coverage of these sensors was coded A9276 (non-covered) and her claim was denied on July 30, 2021. *See* Exhibit E at 4.

III. Statement of Undisputed Material Facts

Prior to January 12, 2017, numerous ALJs had determined that a CGM which does not replace a home glucose monitor was "primarily and customarily used to serve a medical purpose" and was covered "durable medical equipment." *See* Exhibit A at ¶9; AR 38-47.

Prior to January 12, 2017, there was no policy, binding on ALJs and the MAC, precluding ALJs and the MAC from finding that a CGM which does not replace a home glucose monitor is covered "durable medical equipment." *See* Exhibit A at ¶9; AR 38-47.

Prior to January 12, 2017, there was no policy, binding on ALJs and the MAC, precluding ALJs and the MAC from finding that a CGM which does not replace a

home glucose monitor is "primarily and customarily used to serve a medical purpose." *See* Exhibit A at ¶9; AR 38-47.

Prior to January 12, 2017, ALJs and the MAC had discretion to determine that CGMs which do not replace a home glucose monitor are covered "durable medical equipment." *See* Exhibit A at ¶9; AR 38-47.

Prior to January 12, 2017, CMS 1682-R was not published in the FEDERAL REGISTER. *See* Exhibit A at ¶8, Exhibit F at ¶30; Exhibit G at ¶30.

Without notice and comment, on January 12, 2017, CMS issued Ruling No. CMS 1682-R. *See* Exhibit A at ¶8, Exhibit F at ¶30; Exhibit G at ¶30.[4]

CMS 1682-R is CMS' "final opinion and order and statement of policy and interpretation" with regard to CGM coverage. *See* Exhibit B at 1.

CMS 1682-R is "binding on all CMS components [and] on all Department of Health and Human Services components that adjudicate matters under the jurisdiction of CMS." *See* Exhibit B at 1.

CMS 1682-R established the new categories of "therapeutic" and "non-therapeutic" CGMs with regard to coverage. *See* Exhibit B at 6-9.

[4] Because the Secretary neither admitted nor denied this allegation of Paragraph 30 of the Complaint, pursuant to FED.R.CIV.P. 8(b)(6), the Court may deem this allegation admitted. Alternatively, the Court may treat the Secretary's general denial as a denial, in which case it will be the subject of further briefing.

Without notice and comment, CMS 1682-R was incorporated into LCD L33822 and Policy Article A52464. *See* Exhibit C, Exhibit D, Exhibit F at ¶37, Exhibit G at ¶37.

IV. Argument

A. The Complaint and the Secretary's "Answer"

Pursuant to Fed.R.Civ.P. 8(b)(1)(B), a party must admit or deny the allegations asserted against it. Any denials must "fairly respond to the substance of the allegation" (FED.R.CIV.P. 8(b)(2)) and must also be in good faith (in addition to complying with other obligations under the Rules). In addition, if only part of an allegation can be denied in good faith, the defendant must deny only that part and must admit the rest. *See* FED.R.CIV.P. 8(b)(4). A claim that a party lacks knowledge or information to form a belief about the truth of an allegation has the effect of a denial. *See* FED.R.CIV.P. 8(b)(5). If a party fails to deny an allegation, the allegation is deemed admitted. *See* FED.R.CIV.P. 8(b)(6). Importantly, deeming matters admitted as a result of a failure to properly deny is not a sanction. Instead, it is merely the operation of the Rules. *See, e.g., Perez v. El Tequila, LLC.*, 847 F.3d 1247, 1254 (10th Cir. 2017).

With regard to collateral estoppel, the relevant allegations of the Complaint are found at ¶¶ 28-38. Paragraph 30 alleged, in part, that CMS 1682-R issued without notice and comment. *See* Exhibit F. In response, the Secretary neither

admitted nor denied that allegation. *See* Exhibit G. The "Answer" closes with: "The Secretary denies any and all allegations of the complaint not expressly admitted herein." *See* Exhibit G at 23.

For the purposes of the present motion, given the failure to clearly admit or deny the allegation, the allegation should be deemed admitted pursuant to FED.R.CIV.P. 8(b)(6). Alternatively, relying on the general denial, the Court may treat the allegation as denied (in which case additional motion practice will follow).

B. CMS 1682-R Issued Illegally And Is Invalid

There is no genuine issue of material fact that CMS 1682-R established or changed a substantive legal standard concerning the scope of benefits and that CMS 1682-R was not published in the FEDERAL REGISTER for notice and comment 60 days prior to its issuance and effectiveness on January 12, 2017. *See* Exhibit A at ¶8, Exhibit F at ¶30; Exhibit G at ¶30.

By its own terms, CMS 1682-R is a statement of policy and interpretation that articulates CMS' policy concerning classification of CGMS as durable medical equipment. *See* Exhibit B at 1.

Prior to the issuance of CMS 1682-R, ALJs and the MAC had discretion to find coverage of CGMs applying the statutory and regulatory definitions of "durable medical equipment." *See* Exhibit A at ¶9; AR 1403-1412. After the issuance of CMS 1682-R, ALJs and the MAC were precluded from finding coverage for any

CGM that did not meet CMS 1682-R's definition of a "therapeutic" CGM by 42 C.F.R. § 405.1063(b). For example, in this case, ALJ Win held that CMS 1682-R "controls" and that he was "bound" by it. *See* AR31-32. Prior to the issuance of CMS 1682-R, CGMs that did not replace home glucose monitors could be covered as "durable medical equipment" and "primarily and customarily used to serve a medical purpose." *See* Exhibit A at ¶9; AR1403-1412. After the issuance of CMS 1682-R, ALJs and the MAC were bound by CMS 1682-R and had no discretion to determine that CGMs that did not replace home glucose monitors were "durable medical equipment" or were "primarily and customarily used to serve a medical purpose."

As detailed above, CMS 1682-R was never published in the FEDERAL REGISTER and there was never an opportunity for the public to comment prior CMS 1682-R going into effect on January 12, 2017. *See* Exhibit A at ¶8.

Accordingly, CMS 1682-R issued in violation of 42 U.S.C. § 1395hh and "shall [not] take effect." 42 U.S.C. § 1395hh(a)(2). Thus, CMS 1682-R issued illegally, is invalid, and "shall [not] take effect" as a basis to deny Mrs. Smith's claims. Likewise, LCD L33822 and LCA A52464 were not published for notice and comment and, to the extent they incorporate CMS 1682-R, they are also invalid. *See* Exhibit F at ¶37, Exhibit G at ¶37.

C. CMS 1692-R Should be Vacated

In the event that the Court finds that CMS 1682-R issued in violation of law, then, in addition, to declaring it invalid and improperly applied to Mrs. Smith, this Court should vacate CMS 1682-R.

As recognized by both the Tenth Circuit and other Circuits, "when a court finds that an agency regulation is invalid in substantial part, and that the invalid portion, cannot be severed from the rest of the rule, its typical response is to vacate the rule and remand to the agency." *See, e.g., Hospice of New Mexico, LLC. V. Sebelius*, 435 Fed.App'x. 749, 754 (10th Cir. 2011) (*citing Harmon v. Thornburgh*, 878 F.2d 484, 495 (D.C. Cir. 1989)). *See also National Mining Assoc. v. U.S. Army Corps of Engineers*, 145 F.3d 1399 D.C. Cir. 1998):

> The Administrative Procedure Act permits suit to be brought by any person "adversely affect or aggrieved by agency action." In some cases, the "agency action" will consist of a rule of broad applicability; and if the plaintiff prevails, the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual. Under these circumstances a single plaintiff, so long as he is injured by the rule, may obtain "programmatic relief that affects the rights of parties not before the court.

Id. at 1439 (*citing Lujan v. National Wildlife Federation*, 497 U.S. 871, 913 (1990)).

In the present case, CMS 1682-R cannot be severed from itself and the entirety of the Ruling must be vacated. Further, in addition to the claims currently at issue, the Secretary is using CMS 1682-R to deny Mrs. Smith's other claims (*see* Exhibit

E) as well as the claims of others. Accordingly, vacatur of CMS 1682-R is the appropriate relief.

With regard to LCD 33822 and LCA A52464, only those portions relying on CMS 1682-R should be vacated.

V. Conclusion

For the reasons set forth above, the Court should declare that CMS 1682-R issued in violation of 42 U.S.C. § 1395hh, is invalid, and vacate CMS 1682-R. Further, those potions of LCD 33822 and LCA A52464, only those portions relying on CMS 1682-R should be vacated.

Further, pursuant to 42 U.S.C. § 405(g) (fourth sentence), this Court should reverse the Secretary's denial of Mrs. Smith's claims and remand to the Secretary with instructions to provide coverage.

Dated: September 7, 2021

Respectfully submitted,

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